

September 18-20, 2006
Bethesda North Marriott Hotel &
Conference Center
Bethesda, Maryland

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM

ASSESSING CARDIOVASCULAR RISK AND PROGRESSION

PROGRAM AND REGISTRATION

CO-CHAIRS

*Peter Libby, M.D.
Mallinckrodt Professor of Medicine
Harvard Medical School and
Chief Cardiovascular Medicine
Brigham and Women's Hospital*

*Jean-Claude Tardif, M.D., FRCPC, FACC
Director, MHI Research Center
Professor of Medicine
CIHR Chair in Atherosclerosis
Montreal Heart Institute*

The objectives of this program are to:

- *Examine the pathogenesis of cardiovascular disease*
- *Provide information on established and novel biomarkers and imaging technologies*
- *Identify issues in cardiovascular biomarker identification and application*
- *Create efficiencies toward improved patient healthcare*

This meeting is co-sponsored by:

Montreal Heart Institute
and
U.S. Department of Health and Human Services
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition



Montreal Heart Institute
Coordinating Center



Clinical Lynx Inc.

CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM WELCOME

Dear Colleague:

We are pleased to invite you to participate in the 4th Annual Cardiovascular Biomarkers and Surrogate Endpoints Symposium, September 18-20, 2006 at the Bethesda North Marriott Hotel and Conference Center in Bethesda, Maryland. This outstanding scientific program addresses current approaches for assessing and managing cardiovascular risk, as well as state-of-the-art strategies for assessing effects of novel therapeutics for cardiovascular disorders. The meeting will focus on strategies to identify, manage and monitor patients with cardiovascular disease, with special emphasis on the drug development challenges.

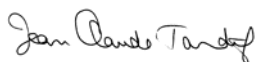
Given the growing prevalence of cardiovascular disease and an expanding population at risk for future events, healthcare systems will likely face more pressure, rather than less, in coming years. We urgently require tools to address the residual burden of cardiovascular risk that represents a major challenge to human health worldwide in the coming decades. Future biomarker efforts are an integral part of this toolbox and must continue to build on knowledge gained from basic research efforts and clinical evaluations, incorporating lessons from past successes and failures. The appropriate application of cardiovascular biomarkers requires an intimate understanding of disease natural history, the mechanism of the intervention, and the characteristics and limitations of the biomarker. The Cardiovascular Biomarkers and Surrogate Endpoints Symposium is designed to share knowledge and encourage the collaborative efforts needed to accelerate the development of improved cardiovascular diagnostics and therapeutic strategies.

Join us to learn how to translate the latest research findings to improvements in the diagnosis, treatment, and prevention of cardiovascular diseases. Presentations from more than 25 thought-leaders will examine the issues surrounding the use of cardiovascular biomarkers and imaging technologies. We wish to express sincere thanks to all of you who have helped get this annual symposium off to a successful start. To keep up the momentum, we encourage everyone to attend this year's annual meeting and to spread the word within your organizations and local institutions. Only with your support can we advance the field of cardiovascular biomarkers and find efficiencies toward the development of new therapeutics.

Sincerely,



Peter Libby
Chief, Cardiology
Brigham and Women's Hospital



Jean-Claude Tardif
Director, Research
Montreal Heart Institute



Therese Heinonen
Associate Director
Montreal Heart Institute
Coordinating Center

CME

The Continuing Medical Education (CME) office of the University of Montreal, Canada designates this an education activity. Each physician should claim only those hours of credit that he/she actually spent in the educational activity. The CME office of the University of Montreal, Canada is fully accredited by the Canadian Association of Medical Schools (CACMS), by the Quebec College of Physicians (QCP), and by reciprocity by the American Council of CME (ACCME). If you would like to receive a statement of credit, you must attend the program and return the credit request and evaluation form provided at the registration desk.

Hotel Accommodations

To secure your room at the Bethesda North Marriott, please contact the Bethesda North Marriott Reservations at www.stayatmarriott.com/CBSES2006/ or call 800-228-9290 or 301-984-0004 and state you are attending the Biomarkers Symposium. A special room rate is available for symposium attendees. Hotel space is limited, so do not delay making your reservations.



Montreal Heart Institute
Coordinating Center



Clinical Lynx Inc.

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM FACULTY

Michelle A. Albert, M.D., M.P.H.

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Children's Hospital Oakland Research Institute
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Berkeley, CA

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Montreal, Quebec Canada

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Houston, TX

Clemens Mittmann, M.D.

Federal Institute for Drugs and Medical Devices
(BfArM)
Bonn, Germany

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Agency for Healthcare Research and Quality
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Deputy Center Director
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Paula R. Trumbo, Ph.D.

Team Leader, Nutrition Science Evaluation
Office of Nutritional Products, Labeling and Dietary
Supplements
Center for Food Safety and Applied Nutrition
US Food and Drug Administration
College Park, MD

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REGISTRATION FORM Registration Deadline—September 15, 2006

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM

Registration Fee: Before July 15, 2006

\$640.00

After July 15, 2006

\$695.00

Government Employees (full-time):

\$175.00

Payment must be received prior to September 15th. Registrations will be confirmed by email or fax. **Participants are responsible for making their own hotel and travel arrangements.**

Please Print

Prefix	First Name	Last Name	Degree Initials
Title		Organization	
Mailing Address		City	State/Province/Region
Billing Address**		City	State/Province/Region
Postal Code	Country	Email Address	
Phone Number		Fax Number	

**Mail completed registration form and check payable to:
Clinical Lynx, Inc., 828 West Grand River Avenue, Brighton, MI, 48116 USA**

PLEASE CONSIDER THIS FORM AN INVOICE.

OR CHARGE (circle one): Visa MasterCard American Express

Expiration Date _____ Account Number _____

Signature _____

***If paying by credit card, billing address must match credit card holder address.**

For CREDIT CARD PAYEES ONLY: To expedite your registration, please fax this form to Clinical Lynx at 810-494-7122

Cancellation and Refund Policy Deadlines

All cancellation requests must be made in writing and sent to Clinical Lynx, Inc. Registrants who submit cancellation requests that are received on or before August 20, 2006 will receive a refund equal to the registration fee paid less a \$100 administrative fee. Registrants who submit cancellation requests that are received between August 21 and September 15, 2006 will receive a refund equal to fifty percent (50%) of the registration fee paid. Cancellation requests received on or after September 16, 2006 will not be honored and no portion of the registration fee will be refunded.

Please note in the event that the 2006 Cardiovascular Biomarkers and Surrogate Endpoints Symposium is abbreviated or cancelled because of fire, explosion, strike, freight embargo, epidemic, catastrophe, act of God, or the act of a public enemy including, but not limited to, an act of any government, de jure or de facto or agency or official thereof, Clinical Lynx, Inc. reserves the right, in its sole discretion to unilaterally terminate the conference. In such cases, the registrant hereby agrees to waive any claim he, she or it may have against Clinical Lynx, Inc. for damages or compensation, including but not limited to fees for registration, housing, airfare and incidental charges.

Contact the Bethesda North Marriott Hotel at: www.stayatmarriott.com/CBSES2006/

REGISTER TODAY—FAX YOUR REGISTRATION FORM TO 810-494-7122
contact us at symposium@clinicallylnx.com for more information.

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM AGENDA OVERVIEW

Monday, September 18th

11:30 a.m. - 12:00 p.m.	Registration and Complimentary Buffet Lunch
12:00 p.m. - 12:45 p.m.	Welcome and Conference Objectives, Dr. Jean-Claude Tardif and Dr. Therese Heinonen
12:45 p.m. - 4:45 p.m.	Scientific Sessions and Expert Panel Discussions
4:45 p.m.	End of Day 1
7:00 p.m.	Meet the Faculty Reception and Dinner (all participants)

Tuesday, September 19th

7:30 a.m. - 11:30 a.m.	Scientific Sessions and Expert Panel Discussions
11:30 a.m. - 12:30 p.m.	Complimentary Buffet Lunch
12:30 p.m. - 4:30 p.m.	Scientific Sessions and Expert Panel Discussions
4:30 p.m.	End of Day 2

Wednesday, September 20th

7:30 a.m. - 11:30 a.m.	Scientific Sessions and Expert Panel Discussions
11:30 a.m. - 12:30 p.m.	Complimentary Buffet Lunch
12:30 p.m. - 3:30 p.m.	Scientific Sessions and Expert Panel Discussions
3:30 p.m.	Closing Remarks

SCIENTIFIC SESSION PRESENTATIONS

Pathogenesis of Atherothrombotic Disease and Biomarker Identification
Biomarkers in Acute Coronary Syndrome
Markers of Thrombosis and Anti-thrombotic Therapy
Biomarkers in Diabetes, Metabolic Syndrome and Renal Disease
Biomarkers in Cerebrovascular Disease
Biomarkers in Heart Failure
Biomarker Discovery and the Challenges of Validation
Surrogate Endpoints in Clinical Trials
Genomic Biomarker Validation and Pharmacogenomic Initiatives at the FDA
Lipoproteins and Other Related Risk Factors
Markers of Dysfunctional HDL in Coronary Artery Disease
Targeted Molecular and Cellular Imaging
The Role of Imaging in Disease Detection and Treatment
Measures of Cardiac Structure and Function by Magnetic Resonance Imaging
Current Status of Disease Assessment with Carotid Ultrasound
Cardiac Computed Tomography Angiography/Positron Emission Tomography
Special Considerations Based on Gender, Age, and Ethnicity
New Insights Based on Technological Advances and Landmark Trials
The FDA Critical Path Initiative - Opportunities and Challenges
The Need for Biomarkers in Drug Development
The Use of Biomarkers for FDA Regulatory Decision Making - Metabolism and Endocrine
The Use of Biomarkers for FDA Regulatory Decision Making - Cardio-Renal
The Use of Biomarkers for FDA Regulatory Decision Making - Health Claims
Canadian Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
European Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
Integrating Biomarkers into Public Healthcare
Clinical Application of Biomarkers
NIH Cardiovascular Biomarker Initiatives
The Balance Between Safety and Efficacy: Biomarkers as Safety Surrogates

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2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM

AGENDA

Monday, September 18th

- 11:30am – 12:00pm Registration and Buffet Lunch
- 12:00pm – 12:15pm Welcome and Conference Objectives
Dr. Jean-Claude Tardif and Dr. Therese Heinonen
- 12:15pm – 12:45pm Keynote address
Dr. Scott Gottlieb
Deputy Commissioner for Medical and Scientific Affairs
United States Food and Drug Administration
- 12:45pm – 1:15pm Pathogenesis of Atherothrombotic Disease and Biomarker identification
Dr. Peter Libby (Brigham and Women's Hospital)
- 1:15pm – 1:45pm Biomarkers in Acute Coronary Syndrome
Dr. David Morrow (TIMI Study Group, Brigham and Women's Hospital)
- 1:45pm – 2:15pm Thrombosis: New Strategies for Anti-thrombotic Therapies
Dr. Bruce Furie (Harvard Medical School)
- 2:15pm – 2:45pm Biomarkers in Diabetes, Metabolic Syndrome and Renal Disease
Dr. Steven Haffner (University of Texas Health Centers)
- 2:45pm – 3:15pm Biomarkers in Cerebrovascular Disease
Dr. Pierre Amarenco (Bichat- Claude Bernard University Hospital)
- 3:15pm – 3:45pm Biomarkers in Heart Failure
Dr. James De Lemos (University of Texas-Southwestern Medical School)
- 3:45pm – 4:45pm **EXPERT PANEL DISCUSSIONS –Moderators: Peter Libby and Allan Jaffe**
(panelists include J.C. Tardif, D. Morrow, B. Furie, S. Haffner, P. Amarenco,
D. Mann and E. Rimm)

Conclusion – Day 1

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM

AGENDA

Tuesday, September 19th

- 7:30am – 8:00am Biomarker Discovery and The Challenges of Validation
Dr. Robert Gerszten (Massachusetts General Hospital)
- 8:00am – 8:30am Surrogate Endpoints in Clinical Trials
Dr. Paul Ridker (Brigham and Women's Hospital)
- 8:30am – 9:00am Genomic Biomarker Validation and Pharmacogenomic Initiatives at the FDA
Dr. Federico Goodsaid (FDA Office of Clinical Pharmacology)
- 9:00am – 9:30am Lipoproteins and Other Related Risk Factors
Dr. H. Bryan Brewer (Cardiovascular Research Institute)
- 9:30am – 10:00am Markers of Dysfunctional HDL in Coronary Artery Disease
Dr. Jay Heinecke (University of Washington)
- 10:00am – 10:30am Targeted Molecular and Cellular Imaging
Dr. Jonathan Lindner (Division of Cardiovascular Medicine)
- 10:30am – 11:30am **EXPERT PANEL DISCUSSIONS – Moderators: Philip Greenland and Paul Ridker**
(panelists include R. Gerszten, P. Ridker, F. Goodsaid, H. B. Brewer, J. Heinecke,
J. Lindner, J. C. Tardif, P. Libby, R. Krauss, and F. Sacks)
- 11:30am – 12:30pm **LUNCH BREAK**
- 12:30pm – 1:00pm The Role of Imaging in Disease Detection and Treatment
Dr. Jean-Claude Tardif (Montreal Heart Institute)
- 1:00pm – 1:30pm Measures of Cardiac Structure and Function by MRI
Dr. Joao Lima (Johns Hopkins Medical School)
- 1:30pm – 2:00pm Current Status of Disease Assessment with Carotid Ultrasound
Dr. Allen Taylor (Walter Reed Army Medical Center)
- 2:00pm – 2:30pm Cardiac CT and CT/PET
Dr. Zahi Fayad (Mount Sinai School of Medicine)
- 2:30pm – 3:00pm Special Considerations Based on Gender, Age and Ethnicity
Dr. Michelle Albert (Harvard Medical School)
- 3:00pm – 3:30pm New Insights Based on Technological Advances and Landmark Trials
Dr. Robert Harrington (Duke University)
- 3:30pm – 4:30pm **EXPERT PANEL DISCUSSIONS – Moderators: Jean-Claude Tardif and Joao Lima**
(panelists include A. Taylor, Z. Fayad, M. Albert, R. Harrington, P. L'Allier,
P. Libby, and L. Appel)
- Conclusion – Day 2

2006 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS SYMPOSIUM

AGENDA

Wednesday, September 20th

- 7:30am – 8:00am The FDA Critical Path Initiative – Opportunities and Challenges
Dr. Douglas Throckmorton (FDA Cardio-Renal)
- 8:00am – 8:30am The Need for Biomarkers in Drug Development
Dr. David G. Orloff (former FDA/Medpace)
- 8:30am – 9:00am The Use of Biomarkers for FDA Regulatory Decision Making – Metabolism and Endocrine
Dr. Mary Parks (FDA Metabolism and Endocrine)
- 9:00am – 9:30am The Use of Biomarkers for FDA Regulatory Decision Making – Cardio-Renal
Dr. Norman Stockbridge (FDA Metabolism and Endocrine)
- 9:30am – 10:00am Canadian Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
Dr. Agnes Klein (Health Canada)
- 10:00am – 10:30am European Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
Dr. Clemens Mittmann (Federal Institute for Drug and Medical Devices)
- 10:30am – 11:00am The Use of Biomarkers for FDA Regulatory Decision Making - Health Claims
Dr. Paula Trumbo (FDA Nutrition Science Evaluation)
- 11:00am - 12:00pm **EXPERT PANEL DISCUSSIONS – Moderators: Robert Harrington and Eric Brass (panelists include D. Throckmorton, D. Orloff, M. Parks, N. Stockbridge, A. Klein, C. Mittmann, and P. Trumbo)**
- 12:00pm – 12:30pm **LUNCH BREAK**
- 12:30pm – 1 :00pm Integrating Biomarkers into Public Healthcare
Dr. Gurbaneet Randhawa (US Agency for Healthcare Research and Quality)
- 1:00pm – 1:30pm Clinical Application of Biomarkers
Dr. Robert Balaban (NHLBI/NIH)
- 1:30pm – 2:00pm NIH Cardiovascular Biomarker Initiatives
Dr. Christopher O'Donnell (NHLB I/NIH)
- 2:00pm – 2:30pm The Balance Between Safety and Efficacy: Biomarkers as Safety Surrogates
Dr. Eric Brass (UCLA Medical Center)
- 2:30pm – 3:30pm **EXPERT PANEL DISCUSSIONS – Moderators: Jean-Claude Tardif and Peter Libby (panelists include G. Randhawa, R. Balaban, C. O'Donnell, E. Brass, P. Greenland, and M. Prescott)**
- 3:30pm Closing Remarks
Drs. Peter Libby and Jean-Claude Tardif

Conclusion – Day 3

Participating Institutions

Agency for Healthcare Research and Quality

Amgen

AstraZeneca

AstraZeneca R & D

AtheroGenic, Inc.

Atherochem

Baylor Heart Clinic, Baylor College of Medicine

Bichat-Claude Bernard Univ Hosp & Med School

Boehringer Ingelheim Pharmaceuticals

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Federal Institute for Drugs & Medical Devices(BfArM)

GE Healthcare

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Harbor-UCLA Medical Center

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Health Canada

I.R.I.S. (Laboratories Servier)

Institut de Recherches Internationales Servier

Johns Hopkins Medical Institutions

Johnson & Johnson

LipoScience, Inc.

Massachusetts General Hospital

Mayo Medical School

Medpace, Inc.

MedStar Research Institute, Cardio Res Institute

Merck & Co., Inc.

Merck Research Laboratories

Merck/Rosetta

Montreal Heart Institute

Mt. Sinai Medical Center

National Institutes of Health

Northwestern University (Feinberg School of Medicine)

Novartis Pharmaceuticals

Novo Nordisk Inc.

Oregon Health & Science University

Ortho-Clinical Diagnostics

Pfizer Inc

PPL Clinic

Roche Diagnostics

Schering-Plough

Sunhealth Research Institute

Surface Logix, Inc.

Tufts University

Union-Plainfield Medical

United States Food and Drug Administration (FDA)

University of Texas Health Centers

University of Texas-Southwestern Medical School

University of Washington

Vivian Medical Spa

Walter Reed Army Medical Center

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